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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/879,257      | 06/12/2001  | Sachiko Yamamoto     | 70281/55,986        | 4822             |

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/879,257

### Applicant(s)

YAMAMOTO ET AL.

### Examiner

Christian L Fronda

### Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 52-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. In the AMENDMENT dated 10/01/2004, applicants have canceled claims 48-51 and have added new claims 52-58.
2. Claims 52-58 are pending and under consideration in this Office Action.
3. The rejection of claims 48-51 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in view of applicants cancellation of these claims in the AMENDMENT dated 10/01/2004. This rejection has been withdrawn. New claims 52-58 do not contain the indefinite phrase "has character that there is a material having binding ability."
4. The rejection of claims 48-51 under 35 U.S.C. 111, first paragraph, as failing to comply with the written description requirement, is moot in view of applicants cancellation of these claims in the AMENDMENT dated 10/01/2004. This rejection has been withdrawn.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 52-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Applicants' arguments filed 10/01/2004 have been fully considered but they are not persuasive. Applicants' position is that new claims 52-58 included the characterization of the enzymes as hybrid glucose-6-phosphate dehydrogenase. The Examiner respectfully disagrees for reasons of record as supplemented below.

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It is not apparent that the modified enzyme as recited in the claims continues to have any glucose-6-phosphate dehydrogenase activity. Thus, the claims are interpreted as not being limited to any glucose-6-phosphate dehydrogenase activity.

The claims are genus claims that are directed toward any hybrid glucose-6-phosphate dehydrogenase of any enzymatic and biological activity having an amino acid sequence of SEQ ID NO:6 that is modified by insertion or substitution in at least one of the recited positions with any peptide comprising SEQ ID NOs:1-5, 46 or 50.

The scope of the claimed genus includes many hybrid enzymes with widely differing enzymatic activities, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of differences in enzymatic activities and biological functions between genus members is permitted.

The specification describes a genetically modified glucose-6-phosphate dehydrogenase (G6PDH) comprising the amino acid sequence of SEQ ID NO: 6 which is modified to have a peptide inserted into at least one specific position selected from the group consisting of the position between amino acid residues 294-295, between amino acid residues 302-303, between amino acid residues 305-306, between amino acid residues 306-307, between amino acid residues 308-309, between amino acid residues 309-310, between amino acid residues 362-393, the N-terminal, and the C-terminal; wherein said modified amino acid sequence with SEQ ID NO: 6 continues to have glucose-6-phosphate dehydrogenase activity, said peptide consists of at least 6 amino acid residues of an amino acid sequence selected from the group consisting of SEQ ID NOs:1-5, 46, and 50; and an anti-CRP antibody binds to the peptide (see Table 1 and examples).

The specification fails to provide a written description of additional representative hybrid enzymes as encompassed by the genus claims. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite the following may overcome the rejection: an isolated and genetically modified glucose-6-phosphate dehydrogenase (G6PDH) comprising the amino acid sequence of SEQ ID NO: 6 which is modified to have a peptide inserted into at least one specific position selected from the group consisting of the position between amino acid residues 294-295, between amino acid residues 302-303, between amino acid residues 305-306, between amino acid residues 306-307, between amino acid residues 308-309, between amino acid residues 309-310, between amino acid residues 362-393, the N-terminal, and the C-terminal; and wherein said peptide consists of at least 6 amino acid residues of an amino acid sequence selected from the group consisting of SEQ ID NOs:1-5, 46, and 50, wherein said modified amino acid sequence with SEQ ID NO: 6 continues to have glucose-6-phosphate dehydrogenase activity”.

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***Conclusion***

7. No claim is allowed.

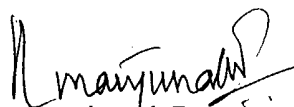
8. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1652

  
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